May 12, 2005

John DiLoreto
Technical Contact
The American Chemistry Council
Acetylene Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Mr. DiLoreto:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Acetylene posted on the ChemRTK HPV Challenge Program Web site on February 26, 2004. I commend The American Chemistry Council Acetylene Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Acetylene

Summary of EPA Comments

The sponsor, the American Chemistry Council's Acetylene Panel, submitted a test plan and robust summaries to EPA for Acetylene (CAS No. 74-86-2) dated December 30, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 26, 2004. The submission included some data on the proposed analog, methylacetylene (CAS No. 74-99-7).

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

2. Health Effects. Adequate data are available for gene mutations for the purposes of the HPV Challenge Program. The data submitted for the repeated-dose toxicity endpoint are not adequate and no data are available for chromosomal aberrations and reproductive/developmental toxicity endpoints. The submitter needs to better support its assertion that the submitted data adequately address all health effects or submit additional data to satisfy these endpoints.

3. Ecological Effects. Because acetylene is a gas that forms highly explosive mixtures in air, in this case, addressing the aquatic toxicity endpoints with the estimated data is acceptable.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Acetylene Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility) and Environmental Fate (photodegradation, stability in water, biodegradation, fugacity

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproduction/developmental toxicity)

The test plan included some data for methylacetylene as an analog for acetylene. EPA considers the proposed analogy to be reasonable.

Adequate data are available for the gene mutation endpoint for the purposes of the HPV Challenge Program. The data provided for the repeated-dose toxicity endpoint are not adequate; two studies on the proposed analog methylacetylene only tested one concentration and no NOAEL was established (ref. 15 of robust summaries). The third study, on acetylene, presented inconsistent data, as the NOAEL was the highest concentration tested with many animals dying at a lower concentration. Higher death rates for some species (e.g., rats) were observed at 250,000 ppm, but no deaths were observed at 800,000 ppm with the same exposure time of one hour (ref. 11 of robust summaries). The submitter did not provide health effects data for acetylene on chromosomal aberrations and reproductive and developmental toxicity endpoints.

The submitter suggests several reasons why reduced testing is justified for acetylene, but the test plan does not include a formal claim for reduced testing as a closed system intermediate (CSI), and acetylene appears unlikely to meet the CSI criteria because of its non-closed system end uses.

Although acetylene is a gas that is difficult to test and limited human and environmental exposure to the chemical is anticipated, there is potential release of acetylene. Repeated human exposure may occur where oxyacetylene torches are used. The submitter's contention that the submitted data adequately address all health effects for acetylene for the HPV Challenge Program is not adequately supported. The submitter states that ". . . as a welding gas where it is combusted, there is only a remote likelihood that human beings can be exposed to meaningful concentrations of acetylene, even in the workplace"; however, no NOAEL was established for rats and dogs tested with a single concentration at 28,700 ppm of methylacetylene (ref. 15), and there seemed to be a trend that more animals died at lower concentrations with longer exposure time than at higher concentrations with shorter exposure time (table 4 on page 10, ref. 11). The submitter needs to provide a better explanation that the data provided have adequately addressed all health effects endpoints or provide additional test data to address health effects for acetylene. It would be helpful for EPA to fully evaluate the submission if any monitoring data for downstream end uses or work places are available.

In addition, the submitter needs to address the following:

(1) Table 5 on page 16 indicates that adequate data are available for chromosomal aberrations and reproductive and developmental toxicities, but no data summaries are provided.

(2) In table 5 there is no distinction between estimated/modeled and measured data.

(3) Under section 4.4.3.2 Chromosomal aberration on page 11, the first bullet is not relevant to genetic toxicity.

Ecological Effects (fish, invertebrates, and algae)

The submitter provided estimated data with some insufficient measured data for fish. Although EPA does not generally consider estimated data to be sufficient without adequate measured data on an analog, given that acetylene is a gas and forms highly explosive mixtures in air, and that the ECOSAR model is considered reliable for this class of substances, addressing the aquatic endpoints with the estimated data alone is reasonable in this case.

Specific Comments on the Robust Summaries

None.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.